

# **Arbutus Presents Corporate Update on Key Milestones**

July 10, 2018

#### First Subject Dosed in Phase 1 Study of AB-506, Arbutus' Second-Generation Capsid Inhibitor All-Oral Combination Study of AB-506 and AB-452 Expected in 2019 HBsAg Reduction Data from ARB-1467 Expected in Q4 Arbutus Spinout Genevant Enters Transformative Partnership with Leading mRNA Therapeutics Company BioNTech

WARMINSTER, Pa., July 10, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today announced updates on several key milestones in advance of the company's presentation at Roivant Pipeline Day in New York City this afternoon. Those updates are as follows:

### AB-506 (Capsid Inhibitor) and AB-452 (RNA Destabilizer) Studies on Track to Support All-Oral Combination Study in 2019

The first subject has been dosed in a clinical trial of AB-506, Arbutus' second-generation capsid inhibitor. The healthy volunteer portion of an innovative Phase 1 study design will be followed by dosing cohorts of HBV patients. The initiation of dosing in HBV patients is expected later this year. Topline results are expected by Q2 2019.

The regulatory filing for AB-452, Arbutus' novel and proprietary RNA destabilizer, is on track for submission in Q3, with subject dosing to follow in Q4. Study completion is expected by Q3 2019. AB-452 was discovered under the leadership of Arbutus' Chief Scientific Officer Dr. Michael J. Sofia, the Lasker Award-winning inventor of sofosbuvir (SOVALDI®). Pending completion of the monotherapy studies for AB-506 and AB-452, Arbutus expects to begin an all-oral combination study in 2H 2019.

"The initiation of our first-in-human study with our next-generation capsid inhibitor is a crucial milestone for Arbutus because of the important role that a potent capsid inhibitor could play in an all-oral therapeutic regimen," said Dr. Sofia. "We are especially excited about advancing our first-in-class RNA destabilizer into a clinical study, setting up for an important all-oral combination study in 2019. We have worked carefully over the past two years to ensure that we are advancing our best and most potent candidates into the clinic."

### **ARB-1467 Interim Results Expected in Q4**

Arbutus also announced that interim 6-week results from Arbutus' ongoing clinical study of ARB-1467 in combination with tenofovir and PEG-IFN are expected in Q4. ARB-1467 is Arbutus' first-generation HBV-RNAi agent. The result of this study will inform small molecule clinical combination studies planned for 2H 2019.

### Patisiran Data and PDUFA Date Set for August 11, 2018

Pivotal study results from Alnylam's APOLLO Phase 3 trial of patisiran have been <u>published</u> in The New England Journal of Medicine (NEJM). Patisiran is currently under Priority Review as a Breakthrough Therapy with the U.S. Food and Drug Administration (FDA). The FDA has set a PDUFA date of August 11, 2018. Successful approval will trigger a royalty entitlement to Arbutus for the proprietary LNP technology licensed by Arbutus to Alnylam for patisiran.

### Genevant Enters Transformative Partnership with BioNTech

Genevant, a recently-launched new company jointly owned by Arbutus and Roivant Sciences, <u>announced</u> today that it has entered into a strategic partnership with BioNTech AG, an industry leader in mRNA therapy development. BioNTech and Genevant will develop five mRNA products for rare diseases with high unmet medical need under a 50/50 co-development and co-commercialization collaboration. Genevant and BioNTech have also agreed a series of exclusive licenses covering the application of Genevant's proprietary delivery technology to five oncology targets, for which Genevant is eligible to receive significant commercial milestones. This partnership advances Genevant's goal of having 5-10 programs in the clinic by 2020 across RNAi, mRNA, and gene editing modalities and positions Genevant as a leader in the development of RNA-based therapeutics.

"This is an exciting time for Arbutus with many pivotal catalysts in the months ahead as we continue our mission of delivering a curative treatment regimen for HBV," said Dr. Mark J. Murray, Arbutus' President and Chief Executive Officer. "I am especially excited about our opportunity to enter all-oral studies in 2019, laying the groundwork for a potentially similar paradigm shift in treatment as we saw in HCV over the past decade. I am also proud of the work we have done to enable the development of additional therapies at Alnylam and at Genevant while retaining significant economic upside for Arbutus."

## **About Arbutus**

Arbutus Biopharma Corporation is a publicly-traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing, and commercializing a cure for patients suffering from chronic Hepatitis B (HBV) infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. For more information, visit www.arbutusbio.com.

#### Forward-Looking Statements and Information

This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Forward-looking statements in this press release include statements about the initiation of a second portion of dosing of AB-506 by year-end, with completion of the study by Q2 2019; the regulatory filing for AB-452 in Q3, with patient dosing to follow in Q4, and study completion expected by Q3 2019; begin an oral combination study of AB-506 and AB-452 in 2H 2019; the importance of a capsid inhibitor in an oral curative HBV therapeutic regimen; interim 6-week results from Arbutus' ongoing clinical study of ARB-1467 in combination with tenofovir and PEG-IFN in Q4; small molecule clinical combination studies in 2H 2019; completion of the FDA's review of patisiran by August 11, 2018, with potential royalties for Arbutus if

approved; BioNTech and Genevant developing five mRNA products for rare diseases with high unmet medical need under a 50/50 co-development and co-commercialization collaboration; Genevant's goal of having 5-10 programs in the clinic by 2020 across RNAi, mRNA, and gene editing modalities; and discovering, developing and commercializing a cure for patients suffering from chronic HBV infection.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical and clinical trials, and the usefulness of the data; the continued demand for Arbutus' assets; the timing of regulatory approvals; the continued availability of key management personnel; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; Arbutus and Genevant may not receive the necessary regulatory approvals for the clinical development of their products on a timely basis, if at all; expected payments, financings, and royalties may not be as large or as timely as expected, if at all; key management personnel may become unavailable; economic and market conditions may worsen; and market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K and Arbutus' continuous disclosure filings, which are available at <u>www.sedar.com</u> and at <u>www.sec.gov</u>. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

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